EXHIBIT A

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FROM: Robert J. Paradiso **PAGES: (including cover sheet) 10**

DATE: March 26, 2004 **Attorney Docket No.: 300.1033US**

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Recipients(s): **Simon J. Oh** ***Fax Number:*** **571-273-0599**

Re: Application of:	Chih-Ming CHEN	Enclosed are:
Serial No.:	09/870,049	- Form PTO-1083 (1 page);
Filed:	October 2, 2001	- Amendment and Statement of Substance of Interview under
For:	PACKAGING SYSTEM	37 CFR §1.133 (8 pages)

MESSAGE:

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Re: Application of:	Chih-Ming CHEN
Serial No.:	09/970,049
Filed:	October 2, 2001
For:	PACKAGING SYSTEM

Enclosed are:
- Form PTO-1083 (1 page);
- Amendment and Statement of Substance of Interview under 37 CFR §1.133 (8 pages)

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FORM PTO-1083

Docket No.: 300.1033US
Date: March 26, 2004

COMMISSIONER FOR PATENTS
Alexandria, VA 22313-1450

In re application of: Chih-Ming CHEN
Serial No.: 09/970,049
Filed: October 2, 2001
For: **PACKAGING SYSTEM**

Sir:

Transmitted herewith is an **Amendment and Statement of Substance of Interview under 37 CFR §1.133** in the above-identified application.

[ ] Small entity status under 37 C.F.R. 1.9 and 1.27 has been previously established.
[ ] Applicants assert small entity status under 37 C.F.R. 1.9 and 1.27.
[X] No fee for additional claims is required.
[ ] A filing fee for additional claims calculated as shown below, is required:

	(Col. 1)	(Col. 2)		SMALL ENTITY			LARGE ENTITY	
FOR:	REMAINING AFTER AMENDMENT	HIGHEST PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	FEE	OR	RATE	FEE
TOTAL CLAIMS	19 Minus 21 =		0	x $ 9	$		x $ 18	$
INDEP. CLAIMS	4 Minus 4 =		0	x $ 42	$		x $ 84	$
[ ] FIRST PRESENTATION OF MULTIPLE DEP. CLAIM				+ $140	$		+ $280	$
				TOTAL:	$	OR	TOTAL:	$

* If the entry in Co. 1 is less than the entry in Col. 2, write "0" in Col. 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

[ ] Also transmitted herewith are:
[ ] Petition for extension under 37 C.F.R. 1.136 (in duplicate)
[ ] Other:

[ ] Check(s) in the amount of **$0.00** is/are attached to cover:
[ ] Filing fee for additional claims under 37 C.F.R. 1.16
[ ] Petition fee for extension under 37 C.F.R. 1.136
[ ] Other:

[X] The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0552.

[X] Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check submitted herewith.
[X] Any patent application processing fees under 37 C.F.R. 1.17.
[X] Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith, and it is hereby requested that this be a petition for an automatic extension of time under 37 CFR 1.136.

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UNITED STATES PATENT AND TRADEMARK OFFICE

Re: Application of:	Chen, Chih-Ming
Serial No.:	09/970,049
Filed:	October 2, 2001
For:	**PACKAGING SYSTEM**
Examiner:	OH, Simon J.

AMENDMENT and STATEMENT OF SUBSTANCE OF INTERVIEW UNDER 37 CFR §1.133

Mail Stop: No-Fee Amendment
Commissioner for Patents
Alexandria, VA 22313-1450

March 26, 2004

Sir:

Reconsideration of the present application in view of the following amendments and remarks is respectfully requested. The undersigned gratefully acknowledges the courtesies extended by Examiners Azpuru and Oh during the interview conducted on March 24, 2004.

I. INTRODUCTORY COMMENTS

This amendment is made in response to the Office Action dated March 9, 2004. The "REMARKS" section of the present amendment includes the substance of the interview as required under 37 CFR §1.133. It is noted that the Remarks section begins on page 7. For the Examiner's convenience, a listing of the pending claims begins on page 2.

II. LISTING OF THE CLAIMS

Claims 1-2. (Cancelled)

3. (Currently amended) A drug packaging system comprising ~~packaging material comprising therein~~ combined prescription drug therapy comprising:

unit dosage forms containing lansoprazole or a pharmaceutically acceptable salt thereof; and

unit dosage forms containing naproxen or a pharmaceutically acceptable salt thereof; ~~and~~

indicia that provides dosing information for administering the lansoprazole or pharmaceutically acceptable salt thereof and naproxen or pharmaceutically acceptable salt thereof; and

packaging material comprising a blister package comprising:

(a) a first set of rupturable substrates and a layer forming blisters over each of the rupturable substrates; each of the blisters containing one of said unit dosage ~~form~~ forms of lansoprazole or pharmaceutically acceptable salt thereof, and

(b) a second set of rupturable substrates and a layer forming blisters over each of the rupturable substrates; each of the blisters containing one of said unit dosage ~~form~~ forms of naproxen or a pharmaceutically acceptable salt thereof.

Claims 4-5. (Cancelled)

6. (Previously presented) The drug packaging system of claim 3, wherein each unit dosage form is independently selected from the group consisting of a tablet, capsule, gel cap, and a caplet.

Claims 7-15. (Cancelled)

16. (Previously presented) The drug packaging system of claim 3 wherein said system comprises unit doses for up to 28 days.

17. (Previously presented) The drug packaging system of claim 3 wherein said system comprises unit doses for 7-14 days.

Claim 18. (Cancelled)

19. (Currently amended) A method of treating a disease or condition comprising:

(a) arranging

unit dosage forms containing lansoprazole or a pharmaceutically acceptable salt thereof; and

unit dosage forms containing naproxen or a pharmaceutically acceptable salt thereof; into

a blister package comprising:

(i) a first set of rupturable substrates and a layer forming blisters over each of the rupturable substrates; each of the blisters containing one of said unit dosage ~~form~~ forms of lansoprazole or pharmaceutically acceptable salt thereof, and

(ii) a second set of rupturable substrates and a layer forming blisters over each of the rupturable substrates; each of the blisters containing one of said unit dosage ~~form~~ forms of naproxen or a pharmaceutically acceptable salt thereof;

to form a drug packaging system;

(b) rupturing one or more substrates to dispense one or more unit doses from the drug packaging system; and

(c) administering said one or more dispensed dosage forms to a human patient according to indicia included in said packaging system, said indicia providing dosing information for administering the lansoprazole or pharmaceutically acceptable salt thereof and naproxen or pharmaceutically acceptable salt thereof; and.

20. (Original) The method of claim 19 which provides therapy for 1-28 days.

Claim 21. (Cancelled)

22. (Previously presented) The drug packaging system of claim 3, wherein the unit dosage forms containing lansoprazole or a pharmaceutically acceptable salt thereof are capsules.

23. (Previously presented) The drug packaging system of claim 3, wherein the unit dosage forms containing naproxen or a pharmaceutically acceptable salt thereof are tablets.

24. (Previously presented) The drug packaging system of claim 3, wherein the unit dosage forms containing lansoprazole comprise 15 mg lansoprazole.

25. (Previously presented) The drug packaging system of claim 3, wherein the unit dosage forms containing naproxen comprise 500 mg naproxen.

Claim 26. (Cancelled)

27. (Amended) The drug packaging system of claim ~~26~~ 3, wherein the indicia is located on the unit dosage forms.

28. (Amended) The drug packaging system of claim ~~26~~ 3, wherein the indicia is located on the blister layers, rupturable substrates or on other packaging material.

29. (Previously presented) The drug packaging system of claim 3, wherein one unit dosage form of lansoprazole or pharmaceutically acceptable salt thereof is suitable for once daily dosing.

30. (Previously presented) The drug packaging system of claim 3, further comprising indicia that provides information to aid with removal of the unit dosage forms.

31. (Previously presented) The drug packaging system of claim 30, wherein the indicia is located on the unit dosage forms.

32. (Previously presented) The drug packaging system of claim 30, wherein the indicia is located on the blister layers, rupturable substrates or on other packaging material.

33. (Currently amended) A drug packaging system comprising ~~packaging material comprising therein~~ combined prescription drug therapy comprising:

unit dosage forms containing lansoprazole or a pharmaceutically acceptable salt thereof; and

unit dosage forms containing an NSAID ~~base~~ or a pharmaceutically acceptable salt thereof; ~~and~~

indicia that provides dosing information for administering the lansoprazole or pharmaceutically acceptable salt thereof and NSAID or pharmaceutically acceptable salt thereof; and

packaging material comprising a blister package comprising:

(a) a first set of rupturable substrates and a layer forming blisters over each of the rupturable substrates; each of the blisters containing one unit dosage form of lansoprazole or pharmaceutically acceptable salt thereof, and

(b) a second set of rupturable substrates and a layer forming blisters over each of the rupturable substrates; each of the blisters containing one unit dosage form of said NSAID ~~base~~ or pharmaceutically acceptable salt thereof.

Please add the following new claims:

34. (New) The drug packaging system of claim 3, wherein the indicia is located on the packaging material.

35. (New) A drug packaging system comprising packaging material comprising therein combined prescription drug therapy comprising one or more unit dosage forms of lansiprazole or a pharmaceutically acceptable salt thereof and one or more unit dosage forms containing naproxen or a pharmaceutically acceptable salt thereof; and

indicia that provides dosing information for administering the lansoprazole or pharmaceutically acceptable salt thereof and naproxen or pharmaceutically acceptable salt thereof.

III. REMARKS

A. Status of the Claims

Claims 3, 6, 16, 17, 19, 20, 22-25 and 27-35 are pending. Independent claims 3, 19 and 33 have been amended to recite the limitations of claim 26 as agreed in the interview. Dependent claims 27 and 28 have been amended to correct dependency.

Support for new claim 34 can be found throughout the original specification as filed, e.g., on page 5, lines 18-24.

Support for new claim 35, e.g., original claims 3, 5 and 7; and page 5, lines 18-24.

It is respectfully submitted that no new matter has been added by virtue of these amendments.

B. Rejection under 35 U.S.C. § 103(a)

In the Office Action, the Examiner rejected the pending claims under 35 U.S.C. §103(a) as being unpatentable over the combined disclosures of W.I.P.O. Publication No. WO 88/02342 to Eek (hereinafter "Eek"); U.S. Patent No. 6,365,184 to Depui *et al.* (hereinafter "Depui"); and U.S. Patent No. 6,253,920 B1 to Kallgren (hereinafter "Kallgren").

During the interview on March 24, 2004, it was discussed that the invention of Depui is directed to two or more different active substances combined in one fixed unit dosage form, as set forth, e.g., at column 2, lines 37-40 of Depui. It was further discussed that this is in contrast to the present invention wherein the two actives are in separate dosage forms.

It was argued during the interview that Depui teaches away from the present invention, e.g., at column 2, lines 36-38, by stating that "administration of two or even more different tablets to the patient is not convenient or satisfactory to achieve the most optimal results." It was respectfully submitted that in view of Depui, one of ordinary skill in the art would not be motivated to keep two drugs in two separate dosage forms as recited in the present claims and would be discouraged from this path.

The Examiners agreed that assuming arguendo that Depui was properly combinable with Eek and Kallgren, the result would be two active agents in a single dosage form, contained in packaging material, rather than the packaging system of the present invention.

Accordingly, as the Examiners deemed Applicant's arguments persuasive in overcoming the prior art rejection during the interview, it is respectfully requested that the obviousness rejection be removed.

IV. CONCLUSION

In view of the arguments presented, it is respectfully submitted that the application is in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully Submitted,
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